TRAINING AND COMMUNICATIONS

STAFF COLLEGE

CONTENTS

PURPOSE This MAPP describes the activities of the Center for Drug Evaluation and Research (CDER) Staff College. The CDER Staff College was created to assist professional staff in maintaining and updating the knowledge and skills they need to help CDER carry out its charge under the Federal Food, Drug, and Cosmetic Act. High-quality professional staff are essential to the protection and promotion of the health of the American people.

Specifically, the Staff College promotes training in the areas of clinical medicine, basic medical sciences, other sciences, and regulatory law as they relate to drug development and review functions.

REFERENCES

- Center for Drug Evaluation and Research (CDER), "Staff College Charter," approved by the Director, February 15, 1988.
- The Accreditation Council for Continuing Medical Education's (ACCME) *Essentials, Guidelines and Standards: For Accreditation of Sponsors of Continuing Medical Education*, October 29, 1982, revised March 20, 1992.

- The American Council on Pharmaceutical Education (ACPE) *Continuing Education Provider Approval Program, Criteria for Quality and Interpretive Guidelines,* July 1991.

DEFINITIONS

- **Staff College:** The Staff College is made up of two parent committees, three subcommittees, and volunteer experts from FDA, other federal government agencies, the regulated drug industry, and academia who serve as members of ad hoc curriculum subcommittees and as faculty in Staff College courses. The Staff College is responsible for the unique education and training needs of all clinical and nonclinical scientific professionals within CDER. The Staff College functions within the Division of Training and Development (DTD).

- **Executive Committee:** This committee is composed of six permanent, one rotating, and several ex-officio members. The Director of CDER is the permanent Executive Committee Chair. Other members include CDER's two Deputy Directors, CDER's Associate Director for Medical Policy, the Director of the Office of Training and Communications (OTCOM), and the Director of DTD. The rotating member is the chair of the Coordinating Committee for Advanced Scientific Education (CCASE) (see below). CDER Office Directors serve as ex-officio members. The Executive Committee confirms the nominations of members of the CCASE and also confirms the chair after she or he has been nominated by CCASE members.

- **Coordinating Committee for Advanced Scientific Education (CCASE):** CCASE serves as the main advisory body to the Director, Division of Training and Development, for all formal scientific and regulatory educational activities directed toward CDER's clinical and nonclinical professionals. CCASE membership comprises 12 professionals representing the major functional professional disciplines within CDER. New members are selected by the existing membership from a pool of respondents to an annual solicitation of interest. Members serve three-year terms.

  Other members of CCASE include representatives from the education subcommittees of each of the various discipline-specific coordinating committees within CDER. Presently, coordinating committees include Chemistry, Manufacturing and Controls; Medical Policy; Pharmacology and

Toxicology; Biopharmaceutics; and Project Management. A specified member of the DTD staff development serves as executive secretary.

POLICY

- The Food and Drug Administration's Center for Drug Evaluation and Research has established the policy of providing opportunities for multidisciplinary continuing education and training in general for all physicians, pharmacists, and other nonclinical professionals, respectively, consistent with the requirements of their duties and within the constraints imposed by available resources.

- CDER's Division of Training and Development and the Staff College are responsible for developing and establishing programs to orient, train, and provide continuing medical education, continuing pharmaceutical education, and continuing education in general. The objective is to provide for the acquisition, standardization, and maintenance of essential knowledge in clinical medicine, basic medical sciences, other sciences, and regulatory law, particularly of the knowledge and skills that will enhance the drug development and review process with the goals of protecting and promoting the health of the American people.

- The DTD and Staff College continuing medical education, continuing pharmaceutical education, and continuing education programs are directed toward these goals.

    1. Bring newly recruited physicians, pharmacists, and other nonclinical reviewing professionals up to a high level of competency in the drug development and regulatory review process in as short a time as possible.

    2. Support physicians in their efforts to maintain state-of-the-art competency in clinical medicine, particularly as it relates to drug development and review.

    3. Support pharmacists and other nonclinical professionals in efforts to maintain state-of-the-art competencies in the pharmaceutical sciences and other regulatory sciences, respectively, in particular as those competencies relate to drug development and review.

    4. Develop and coordinate administrative, executive, and leadership skills programs that enhance professional staffs' ability to complete the regulatory review process more efficiently.

- The Staff College maintains continuing educational efforts in a variety of forms, including (1) written functional training modules or guidance in drug regulatory science; (2) a curriculum of didactic courses and seminars focusing on drug development and review; and (3) workshops and symposia that focus on controversial topics and consensus development in drug development and review.

RESPONSIBILITIES

- **Executive Committee:** This committee serves as the main oversight body for the educational activities of the Staff College. The Executive Committee's main mission is to review and approve the educational programs of the Staff College.

- **Coordinating Committee for Advanced Scientific Education (CCASE):** CCASE serves as the main advisory body to the Director, DTD, for all formal scientific and regulatory educational activities directed toward CDER's clinical and nonclinical professionals, including formal didactic courses and the weekly CDER seminar series. Proposed courses offering accreditation for either or both continuing medical (CME) or pharmaceutical (CPE) education must be reviewed and approved by CCASE. (See discussion below on accreditation.)

- **Subcommittees:** Each of the three formal CCASE subcommittees are composed of at least two members of the parent committee, one of whom is named chair by the chair of CCASE. Other members are selected as needed by the subcommittee chair from a pool of interested clinical and nonclinical professional staff.

  Core Curriculum Subcommittee: This subcommittee is charged with refining and coordinating the basic formal course offerings for new clinical and nonclinical professionals. Its primary goal is to provide a comprehensive program for new review professionals and fellows.

  Technology Curriculum Subcommittee: This subcommittee is charged with ensuring that CDER's clinical and nonclinical professionals obtain the highest quality state-of-the-art training in new technologies and major advances in the sciences.

  Quality Assurance Subcommittee: This subcommittee is charged with

(1) assisting in determining educational needs for CDER's clinical and nonclinical professionals, (2) ensuring that courses and seminars meet the needs of CDER's clinical and nonclinical professionals, (3) ensuring that all programs meet the criteria for medical (CME) and pharmaceutical (CPE) continuing education credit, and (4) overseeing DTD's maintenance of supporting documentation for continuing medical (CME) and pharmaceutical (CPE) education certification.

- **Director, Division of Training and Development (DTD):** The Director of the DTD is responsible for the overall coordination of the Staff College's committee structure and oversees the alignment of DTD staff to support the needs and functions of the committees. The director compiles an annual summary of activities for submission to the Executive Committee.

- **Division of Training and Development (DTD):** The DTD staff provide line support and technical assistance to the various Staff College committees. For detailed information on the DTD's other responsibilities, contact the DTD.

- **Faculty:** Staff College faculty serve at least one year on standing parent committees of the College. They organize and teach Staff College programs or compose the professional interactive networks. Staff College faculty are recognized as "Associates" of the Staff College with a formal certificate conferred by the Director and Executive Committee.

- **Affiliated Committee:** The Society of FDA Pharmacists: This group is affiliated with the Staff College for CPE credit through the CCASE Committee. A liaison member of this organization is invited to participate in a nonvoting capacity.

ACCREDITATION

CDER is recognized as sponsor and provider of continuing medical education (CME) and continuing pharmaceutical education (CPE) credit by the Accreditation Council for Continuing Medical Education (ACCME) and the American Council on Pharmaceutical Education (ACPE), respectively. Credit can be received for programs reviewed and approved by the College's CCASE committee.

JOINT OR COSPONSORSHIP

CDER's Staff College has established the following official policy regarding continuing education credit for (1) jointly sponsored continuing medical education (CME) activities and (2) cosponsored continuing pharmaceutical education (CPE) activities.

- Any activity that is jointly sponsored or cosponsored by CDER must be consistent with CDER's and the Staff College's mission statements and educational program goals. An evaluation of each jointly sponsored or cosponsored continuing education activity must be made within the contexts of CDER and Staff College goals.

- When jointly sponsoring or cosponsoring an educational activity, CDER, through its Staff College, will meet the requirements of Essential # 7 of ACCME's *Essentials, Guidelines and Standards: For Accreditation of Sponsors of Continuing Medical Education* and Quality Criteria 3 and 4 of ACPE's *Continuing Education Provider Approval Program: Criteria for Quality and Interpretive Guidelines*.

  These requirements call for the "sponsor" (ACCME definition) or "provider" (ACPE definition) to participate integrally in the educational needs assessment and topic selection, learning objectives design, planning, development, implementation, and evaluation of each jointly sponsored CME activity or cosponsored CPE activity. CDER will ensure that ACCME and ACPE accreditation standards and quality criteria are met by the continuing education activities it jointly sponsors or cosponsors with nonaccredited institutions and organizations. CDER assumes the same responsibility for activities it sponsors jointly or independently.

STANDARDS FOR COMMERCIAL SUPPORT

CDER's Staff College has established the following policies on commercial support of continuing education activities.

- CDER, through its Staff College, will meet the *Standards for Commercial Support of CME* and Quality Criterion 17 of the *Criteria for Quality and Interpretive Guidelines* as prescribed by ACCME and ACPE, respectively.

- CDER, through its Staff College, will be responsible for the content, quality, and scientific integrity of all multidisciplinary continuting education certified for credit. CDER, through its Staff College, assumes responsibility for the identification of needs; determination of educational objectives; and selection

of content, faculty, educational methods, and materials.

- Course evaluation will be designed and performed by the Staff College.
- All programs shall provide for an in-depth presentation with fair, full disclosure and equitable balance.
- Appropriate topics and learning activities will be distinguished from topics and learning activities that are promotional or appear to be intended for the purpose of endorsing either a specific commercial drug or other commercial product (as contrasted with the generic product/drug entity and its contents or the general therapeutic area it addresses), or a specific commercial service (as contrasted with the general service area and/or the aspects or problems of professional practice it addresses).
- In designing educational activities, the Staff College will ensure that activities are free of commercial bias of any kind. If they deal with commercial products, activities will present information about those products objectively, based on scientific methods generally accepted in the medical community.
- The design and production of educational activities shall be the ultimate responsibility of the Staff College. Commercial supporters of such activities should not control the planning, content, or execution of any activity.
- CDER and its Staff College must remain completely independent and, therefore, do not accept funds from commercial sources. In addition, CDER has a policy requiring the disclosure of any financial or other interests a faculty member may have with the manufacturer(s) of a commercial product(s) discussed in an educational presentation. The existence of CME and CPE faculty relationships with commercial supporters are disclosed to participants prior to each educational activity, and brief statements clarifying such relationships are provided in conference materials such as brochures, syllabi, exhibits, poster sessions, and in any postmeeting publications.

EFFECTIVE DATE

This MAPP is effective upon date of publication.